ಔಷಧಗಳ ಗುಣಮಟ್ಟ ಪರೀಕ್ಷೆ

3261 (1542); ಡಾ॥ ಅಶ್ವಥ್ ನಾರಾಯಣ ಸಿ.ಎನ್. (ಮಲ್ಲೇಶ್ವರಂ)

ಅ) ಸರ್ಕಾರಿ ಆಸ್ಪತ್ರೆಗಳಿಗೆ ಸರಬರಾಜು ಮಾಡುವ ಔಷಧಿಗಳ ಗುಣಮಟ್ಟ ಪರೀಕ್ಷೆಗಾಗಿ ಕೈಗೊಳ್ಳಲಿರುವ ಕ್ರಮಗಳೇನು; (ವಿವರ ಒದಗಿಸುವುದು);

ಆ) ಇವುಗಳ ಗುಣಮಟ್ಟದಲ್ಲಿ ಪ್ರಮಾಣದಲ್ಲಿ ವ್ಯತ್ಯಾಸವಿದ್ದಲ್ಲಿ ಸರ್ಕಾರ ಕೈಗೊಳ್ಳುವ ಕ್ರಮಗಳು ಏನು; (ವಿವರ ನೀಡುವುದು);

ಇ) ಕಳೆದ ಎರಡು ವರ್ಷಗಳಿಂದ ಸರ್ಕಾರಿ ಆಸ್ಪತ್ರೆಗಳಿಗೆ ಸರಬರಾಜು ಮಾಡಿರುವ ಕಬ್ಬಿಣಾಂಶದ ಮಾತ್ರೆಗಳ ಗುಣಮಟ್ಟದ ಖಾತ್ರಿಯ ಬಗ್ಗೆ ಪರೀಕ್ಷೆ ನಡೆಸಲಾಗಿದೆಯೇ; ನಡೆಸಿದ್ದರೆ ದಾಖಲಾತಿಗಳೊಂದಿಗೆ ವಿವರ ನೀಡುವುದು;

ಈ) ರಾಜ್ಯದಲ್ಲಿ ರಕ್ತ ಹೀನತೆಯಿಂದ ಬಳಲುತ್ತಿರುವ ಮಹಿಳೆಯರು/ ಬಾಣಂತಿಯರು/ಮಕ್ಕಳು ಇವರಿಗೆ ನೀಡುವ ಕಬ್ಬಿಣಾಂಶದ ಮಾತ್ರೆಗಳು ದೋಷಪೂರಿತವಾಗಿರುವುದು ಸರ್ಕಾರದ ಗಮನಕ್ಕೆ ಬಂದಿದೆಯೇ?

ಶ್ರೀ ಯು.ಟಿ. ಖಾದರ್ (ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸಚಿವರು)

ಅ) ಔಷಧ ನಿಯಂತ್ರಣ ಇಲಾಖೆಯ ಅಮಲುಜಾರಿ ಅಧಿಕಾರಿಗಳು ರಾಜ್ಯದಲ್ಲಿ ಸರ್ಕಾರಿ ಮತ್ತು ಖಾಸಗಿ ಆಸ್ಪತ್ರೆಗಳನ್ನೊಳಗೊಂಡಂತೆ ಲಭ್ಯವಾಗುವ ಔಷಧ ಗುಣಮಟ್ಟವನ್ನು ಖಾತ್ರಿ ಪಡಿಸುವ ನಿಟ್ಟಿನಲ್ಲಿ ರ್ಯಾಂಡಂ ಬೇಸಿಸ್ ಮೇರೆಗೆ ಔಷಧ ಮಾದರಿಗಳನ್ನು ಪಡೆದು ರಾಜ್ಯ ಔಷಧ ಪರೀಕ್ಷಾ ಪ್ರಯೋಗಾಲಯಗಳಿಗೆ ವಿಶ್ಲೇಷಣೆಗಾಗಿ ಕಳುಹಿಸಲಾಗುವುದು.

ಆ) ಔಷಧ ಮತ್ತು ಕಾಂತಿವರ್ಧಕ ಅಧಿನಿಯಮ ಸೆಕ್ಷನ್ 33 (P) ಅಡಿಯಲ್ಲಿ ಕೇಂದ್ರ ಸರ್ಕಾರವು ಗುಣಮಟ್ಟವಲ್ಲದ ಔಷಧಗಳ ಕುರಿತು ಕ್ರಮ ಜರುಗಿಸಲು ತಯಾರಿಕಾ ಸಂಸ್ಥೆ ಇರುವ ರಾಜ್ಯದ ಔಷಧ ನಿಯಂತ್ರಕರು ಮತ್ತು ಪರವಾನಗಿ ಪ್ರಾಧಿಕಾರಿಗೆ ತಯಾರಕರ ವಿರುದ್ಧ

ಕ್ರಮ ಜರುಗಿಸಲು ಕೋರಲಾಗುತ್ತದೆ ಹಾಗೂ ಮೊಕದ್ದಮೆ ದಾಖಿಲುಪಡಿಸುವುದಲ್ಲದೆ ಇಲಾಖಾ ಕ್ರಮಗಳನ್ನೂ ಸಹ ಜರುಗಿಸಲು ಕ್ರಮ ಕೈಗೊಳ್ಳಲಾಗುವುದು.

ಇ) ಹೌದು, ಸರ್ಕಾರಿ ಆಸ್ಪತ್ರೆಗಳಿಗೆ ಸರಬರಾಜು ಮಾಡಿರುವ ಕಬ್ಬಿಣಾಂಶದ ಮಾತ್ರೆಗಳನ್ನು ಗುಣವಿಶ್ಲೇಷಣೆಗೆ ಒಳಪಡಿಸಿ, ಅದರ ವರದಿಯ ಪ್ರಕಾರ ಉತ್ತಮ ಗುಣಮಟ್ಟದ ಔಷಧಿಯೆಂದು ಘೋಷಿಸಲ್ಪಟ್ಟಿದೆ.

ಈ) ಗುಣ ವಿಶ್ಲೇಷಣೆಗೆ ಒಳಪಡಿಸಿದ ಕಬ್ಬಿಣಾಂಶ ಮಾತ್ರೆಗಳ (Test Report) ದಾಖಿಲಾತಿಗಳನ್ನು ಲಗತ್ತಿಸಿದೆ.

STANDARD ANALYTICAL LABORATORY (ND) PVT. LIMITED

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Govt. Approved Website : www.standardanalytical.com

TEST REPORT Approval No. 19/LAB

(FORM 29)
(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

C

Sample Name	IRON & FOLIC ACID TABLETS.**	Mfg Lic No	N.S.
Submitted By	DIRECTOR, KSD.L&WAREHOUSING SOCIETY Bangalore	Report No	SALT07012015143
Address	1, Dr. SiddaiahPuraniRoad, RHB.ColonyNagadiRoad	Receipt Date	07-Jan-15
Mfg By	N.S.	Report Date	14-Jan-15
Supplied By	N.S.	Ref No	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-216	01/09/2014	28/02/2016	N.S.	60 TABS.

IP 2014

RESULT OF ANALYSIS

Date / Period of Performance of test 07/01/2015 to 14/01/2015.
***KDLWS/CS/16/2014-15. DATED:- 29/12/2014.

Reference to protocol :- I.P-2014.(**Iron & Folic Acid Tablets-IP)

Description :- Blue coloured round biconvex enteric coated tablets.

Identification :-
for Folic Acid by (HPLC). :- Complies.
For Dried Ferrous Sulphate
(by Chemical) :- Complies.
Average weight :- 443.5mg.
Uniformity of weight :- Within limit(441.7mg. to 445.7mg.)
Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.
Disintegration time :-
1.Acidic medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 22 to 23 minutes. (Limit NET 60 minutes)

Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	99.03mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	0.521mg	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned, The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Person In Charge Of Testing

NOTE: 1 The result listed refer only to the listed samples and applicable parameters tested/examined at laboratory unless otherwise stated
2 Samples not drawn by us. Total liability of this laboratory limited to the invoice amount
3 The report is not to be reproduced wholly or in part and cannot be used as an evidence in the Court of Law and should not be used in any advertising media without special permission in writing

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Website: www.standardanalytical.com

TEST REPORT Approval No.: 12/LAB

FORM 25

(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name	IRON & FOLIC ACID TABLETS.**	Mfg Lic No	N.S.
Submitted By	DIRECTOR,KSD.LWAREHOUSING SOCIETY Bangalore	Report No	SALT07012015144
Address	1,Dr.SiddalahPuranikRoad,KHB.ColonyNagadiRoad	Receipt Date	07-Jan-15
Mfg By	N.S.	Report Date	14-Jan-15
Supplied By	N.S.	Ref No	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-Z18	01/09/2014	28/02/2016	N.S.	60 TABS.

IF 11427

RESULT OF ANALYSIS

Date / Period of Performance of test 07/01/2015 to 14/01/2015.

***KDLMS/CS/16/2014-15. DATED:- 29/12/2014.

Reference to protocols	:- I.P-2014.(**Iron & Folic Acid Tablets-IP)				
Description	:- Blue coloured round biconvex enteric coated tablets.				
Identification	:-				
for Folic Acid by (HPLC)	:- Complies.				
For Dried Ferrous Sulphate (by Chemical)	:- Complies.				
Average weight	:- 452.5mg.				
Uniformity of weight	:- Within limit(450.7mg. to 454.8mg.)				
Uniformity of content(by HPLC) for Folic Acid	:- Within limit.				
Disintegration time	:-				
1.Acidic medium	:- Passes the test (Limit NLT 2 hours)				
2.Buffer medium	:- 23 to 24 minutes. (Limit NMT 60 minutes)				
Ferric Iron	:- Complies.				
Assay	:- Each enteric coated tablet contains:-				
Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous Iron	:- 98.61mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.519mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per-IP.

Dr R. N. TRIPATHI

Person In Charge Of Testing

NOTE 1 The result listed relate only to the tested samples and applicable parameter. Endorsement of products is neither intended nor implied

2 Sample not drawn by us. Total liability of this laboratory limited to the invoice amount

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STANDARD ANALYTICAL LABORATORY (ND) PVT. LIMITED

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Ph.: 011-22142265, 22142266 Fax: 011-43134472 E-mail: ...

Govt. Approved Testing House

TEST REPORT Approval No: 1V/LAB

FORM 29 (THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name	IRON & FOLIC ACID TABLETS.**	Mfg Lic No	N.S.
Submitted By	DIRECTOR, KSD. LAWAREHOUSING SOCIETY Bangalore	Report No	SALT07012015145
Address	1, Dr. SiddaiahPuranikRoad, KHB. ColonyNagadiRoad	Receipt Date	07-Jan-15
Mfg By	N.S.	Report Date	14-Jan-15
Supplied By	N.S.	Ref No	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-220	01/09/2014	28/02/2016	N.S.	60 TABS.

IF/14419

RESULT OF ANALYSIS

Date / Period of Performance of test 07/01/2015 to 14/01/2015.
***KDLMS/CS/16/2014-15. DATED:- 29/12/2014.

Reference to protocol	:- I.P-2014; (**Iron & Folic Acid Tablets-IP)				
Description	:- Blue coloured round biconvex enteric coated tablets.				
Identification	:-				
for Folic Acid by (HPLC)	:- Complies.				
For Dried Ferrous Sulphate (by Chemical)	:- Complies.				
Average weight	:- 427.5mg.				
Uniformity of weight	:- Within limit(425.7mg. to 429.5mg.)				
Uniformity of content(by HPLC)	:-				
for Folic Acid	:- Within limit.				
Disintegration time	:-				
1.Acidic medium	:- Passes the test (Limit NLT 2 hours)				
2.Buffer medium	:- 21 to 22 minutes. (Limit NMT 60 minutes)				
Ferric Iron	:- Complies.				
Assay	:- Each enteric coated tablet contains:-				
			LIMIT		
Contents of	Obtd./Av.wt.	Claim	Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous Iron	:- 99.17mg	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.522mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

ort: In Opinion of the undersigned, The sample referred to above is of Standard Quality defined in the Act and the rules made there under for the reason given: Complies as IP.

Person In Charge Of Testing

NOTE: 1 The result listed refer only to the items submitted for analysis. Unless otherwise specified, samples are not drawn by us. Total liability of this laboratory limited to the invoice amount.
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STANDARD ANALYTICAL LABORATORY (ND) PVT. LIMITED

TEST REPORT Approval No.: 13/LAB

FORM-30

(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name	Ferrous Sulphate & Folic Acid Tablets.(Large)	**Mfg Lic No**	N.S.
Submitted By	DIRECTOR,KSD.LaWAREHOUSING SOCIETY Bangalore	**Report No**	SALT23122014122
Address	1,Dr.SiddaiahPuranikRoad,KHB.ColonyMagadiRoad	**Receipt Date**	23-Dec-14
Mfg By	N.S.	**Report Date**	30-Dec-14
Supplied By	N.S.	**Ref No**	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-099	06/2014	11/2015	N.S.	60 TABS.

DF/14029 **RESULT OF ANALYSIS**

Date / Period of Performance of test 23/12/2014 to 30/12/2014.
***KDWS/CS/16/2014-15. DATED:- 11/12/2014.

Reference to protocol :- I.P-2014.(Iron & Folic Acid Tablets-IP)

Description :- Blue round biconovex enteric caoted tablets.

Identification :-
for Folic Acid by (HPLC) :- Complies
For Dried Ferrous Sulphate
(by Chemical) :- Complies

Average weight :- 430.9mg
Uniformity of weight :- Within limit(428.3mg to 433.4mg)
Uniformity of content(by HPLC):-
for Folic Acid :- Within limit
Disintegration time :-
1.Acidic medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 21 to 22 minutes. (Limit NMT 60 minutes)

Ferric Iron :- Complies

Assay :- Each enteric coated tablet contains:-

		LIMIT		
Contents of	Obtd./Av.wt.	Claim	Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	:- 99.0mg	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.518mg	0.5mg.	0.45mg.	-	IP.

NOTE:-SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Person In Charge Of Testing

NOTE 1 The result listed refer only to the tested samples and applicable parameter. Endorsement of product is neither inferred nor implied
2 Sample not drawn by us. Total liability of the laboratory limited to the invoice amount
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STANDARD ANALYTICAL LABORATORY (ND) PVT. LIMITED

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TEST REPORT

Approval No. : 1317/AD

FORM-38
(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

c

Sample Name	Ferrous Sulphate & Folic Acid Tablets.(Largo)	**Mfg Lic No**	N.S.
Submitted By	DIRECTOR,KSD.L&WAREHOUSING SOCIETY Bangalore	**Report No**	SALT23122014123
Address	1,Dr.SiddaiahPuronikRoad,KHB.ColonyNagadiRoad	**Receipt Date**	23-Dec-14
Mfg By	N.S.	**Report Date**	30-Dec-14
Supplied By	N.S.	**Ref No**	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-V02	06/2014	11/2015	N.S.	60 TABS.

(FL1403) **RESULT OF ANALYSIS**

Date/Period of Performance of test 23/12/2014 to 30/12/2014.
***KDMRS/CS/16/2014-15. DATED:- 11/12/2014.

Reference to protocol :- I.P-2014.(Iron & Folic Acid Tablets-IP)

Description :- Blue, round, biconvex, enteric, coated tablets.

Identification :-
for Folic Acid by (HPLC). :- Complies.
For Dried Ferrous Sulphate (by Chemical) :- Complies.

Average weight :- 430.8 mg.
Uniformity of weight :- Within limit (428.3mg to 433.6mg)

Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.
Disintegration time :-
1.Acidic-medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 17 to 18 minutes. (Limit NMT 60 minutes)
Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	:- 99.1mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.519mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Person In Charge Of Testing

NOTE 1 The result listed refer only to the tested samples and applicable parameter. Endorsement of products is neither inferred nor implied.
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TEST REPORT

Approval No.: 12/LAB

FORM 39

(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name	Ferrous Sulphate & Folic Acid Tablets. (Large)	Mfg Lic No	N.S.
Submitted By	DIRECTOR, KSD. & WAREHOUSING SOCIETY Bangalore	Report No	SALT23122014121
Address	1, Dr. Siddaiah Puranik Road, KHB. Colony Nagadi Road,	Receipt Date	23-Dec-14
Mfg By	N.S.	Report Date	30-Dec-14
Supplied By	N.S.	Ref No	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-D97	06/2014	11/2015	N.S.	60 TABS.

DFL/4904

RESULT OF ANALYSIS

Date/Period of Performance of test 23/12/2014 to 30/12/2014.

***KDLWS/CS/16/2014-15. DATED:- 11/12/2014.

Reference to protocol :- I.P-2014. (Iron & Folic Acid Tablets-IP)

Description :- Blue, round, biconvex, enteric, coated tablets.

Identification :-
for Folic Acid by (HPLC) :- Complies.
For Dried Ferrous Sulphate
(by Chemical) :- Complies.

Average weight :- 422.8 mg.
Uniformity of weight :- Within limit (420.2mg to 425.5mg)
Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.

Disintegration time :-
1. Acidic medium:- Passes the test (Limit NLT 2 hours)
2. Buffer medium:- 18 to 19 minutes. (Limit NMT 60 minutes)

Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron :-	99.5mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid :-	0.520mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report: In Opinion of the undersigned, The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

RIPATH

Person In Charge Of Testing

NOTE: 1. The result listed refer only to the tested samples, and applicable parameters. Endorsement of products is neither inferred nor implied
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69, FUNCTIONAL INDUSTRIAL ESTATE, PATPARGANJ, DELHI-110092

TEST REPORT

Approval No. 19/LAB

FORM-38

(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

C

Sample Name	Ferrous Sulphate & Folic Acid Tablets.(Large)	**Mfg Lic No**	N.S.
Submitted By	DIRECTOR,KSD.LAWAREHOUSING SOCIETY Bangalore	**Report No**	SALT23122014070
Address	1,Dr.SiddaiahPuranikRoad,KHB.ColonyMagadiRoad	**Receipt Date**	23-Dec-14
Mfg By	N.S.	**Report Date**	30-Dec-14
Supplied By	N.S.	**Ref No**	***

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-T96	07/2014	12/2015	N.S.	60 TABS.

IFL/14058

RESULT OF ANALYSIS

Date / Period of Performance of test 23/12/2014 to 30/12/2014.

***KDLWS/CS/16/2014-15. DATED:- 11/12/2014.

Reference to protocol :- I.P-2014. (Iron & Folic Acid Tablets-IP)

Description :- Grey coloured round biconvex enteric coated tablets.

Identification :-

for Folic Acid by (HPLC) :- Complies.

For Dried Ferrous Sulphate (by Chemical) :- Complies.

Average weight :- 441.5mg.

Uniformity of weight :- Within limit(439.5mg to 443.9mg)

Uniformity of content(by HPLC) for Folic Acid :- Within limit.

Disintegration time :-

1.Acidic medium:- Passes the test (Limit NLT 2 hours)

2.Buffer medium:- 23 to 24 minutes. (Limit NMT 60 minutes)

Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	98.7mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	0.515mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Person In Charge Of Testing

Dr.R.N TRIPATHI

NOTE 1 The results relate only to the tested samples and applicable parameters. Endorsement of products is neither inferred nor implied.
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TEST REPORT Approval No. : 19/LAB

FORM 29

(THE DRUGS & COSMETICS ACT 1940 & RULES THEREUNDER)

Sample Name	Ferrous Sulphate & Folic Acid Tablets.(Large)	**Mfg Lic No**	N.S.
Submitted By	DIRECTOR,KSD.LSWAREHOUSING SOCIETY Bangalore	**Report No**	SALT23122014071
Address	1,Dr.SiddaiahPuranikRoad,KHB.ColonyNagadiRoad	**Receipt Date**	23-Dec-14
Mfg By	N.S.	**Report Date**	30-Dec-14
Supplied By	N.S.	**Ref No**	

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-T98	07/2014	12/2015	N.S.	60 TABS.

IFL110558

RESULT OF ANALYSIS

Date / Period of Performance of test 23/12/2014 to 30/12/2014.
***KDLMS/CS/16/2014-15. DATED:- 11/12/2014.

Reference to protocol	:-	I.P-2014.(Iron & Folic Acid Tablets-IP)
Description	:-	Grey coloured round biconvex enteric coated tablets.
Identification	:-	
for Folic Acid by (HPLC)	:-	Complies.
For Dried Ferrous Sulphate (by Chemical)	:-	Complies.
Average weight	:-	445.6mg.
Uniformity of weight	:-	Within limit(443.7mg. to 447.9mg.)
Uniformity of content(by HPLC)	:-	Within limit.
for Folic Acid	:-	
Disintegration time	:-	
1.Acidic medium	:-	Passes the test (Limit NLT 2 hours)
2.Buffer medium	:-	25 to 26 minutes. (Limit NMT 60 minutes)
Ferric Iron	:-	Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	98.6mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	0.524mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Dr. P. N TRIPATHI

Person In Charge Of Testing

NOTE: 1.The result listed refer only to the tested samples and applicable parameters. Endorsement of products is neither intended nor implied.
2. Samples not drawn by us. Total liability of this laboratory limited to the invoice amount.
3. This report is not to be reproduced wholly or in part and cannot be used as an evidence in the Court of Law and should not be used in any advertising media without special permission in writing.

STANDARD ANALYTICAL LABORATORY (ND) PVT. LIMITED

60, FUNCTIONAL INDUSTRIAL ESTATE, PATPARGANJ, DELHI-110092

Ph.: 011-22745265, 22148208 Fax: 011-43528272 E-mail: standardanalytical@yahoo.com

TEST REPORT

FORM-25

(THE DRUGS & COSMETICS ACT, 1940 & RULES THEREUNDER)

Approval No.: 13/LAB

C

Sample Name	Ferrous Sulphate & Folic Acid Tablets.(Large)	**Mfg Lic No**	N.S.
Submitted By	DIRECTOR,KSD.L&WAREHOUSING SOCIETY Bangalore	**Report No**	SALT23122014072
Address	1,Dr.SiddaiahPuranikRoad,KHB.ColonyNagadiRoad	**Receipt Date**	23-Dec-14
Mfg By	N.S.	**Report Date**	30-Dec-14
Supplied By	N.S.	**Ref No**	

Batch No	Mfg. Date	Exp Date	Batch Size	Sample Qty
13-T100	07/2014	12/2015	N.S.	60 TABS.

TF-L 18/060 **RESULT OF ANALYSIS**

Date / Period of Performance of test 23/12/2014 to 30/12/2014.
***KDLWS/CS/16/2014-15. DATED:- 11/12/2014.

Reference to protocol :- I.P-2014.(Iron & Folic Acid Tablets-IP)

Description :- Grey coloured round biconvex enteric coated tablets.

Identification :-
for Folic Acid by (HPLC) :- Complies.
For Dried Ferrous Sulphate
(by Chemical) :- Complies.

Average weight :- 443.6mg.
Uniformity of weight :- Within limit(441.6mg. to 445.5mg)

Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.

Disintegration time :-
1.Acidic medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 24 to 25 minutes. (Limit NMT 60 minutes)
Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT* Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	99.2mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	0.519mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Dr.R.N. TRIPATHI

Person In Charge Of Testing

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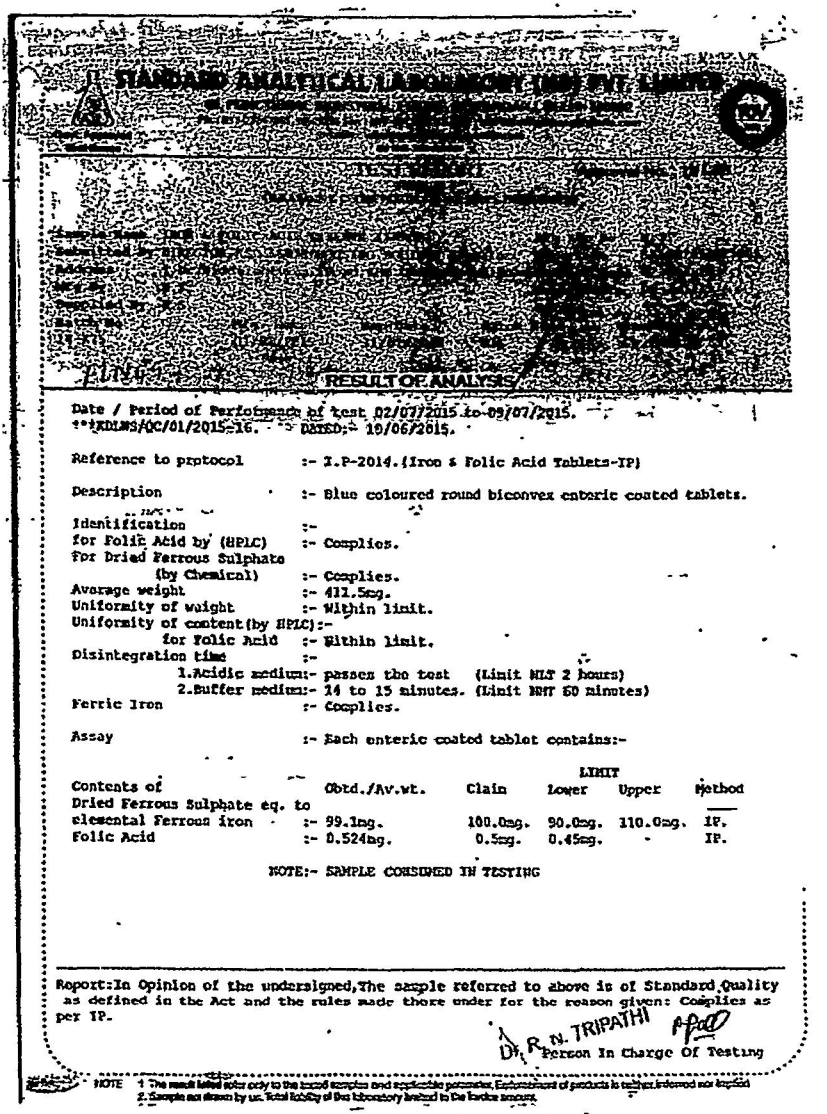

STANDARD ANALYTICAL LABORATORIES (I) PVT. LIMITED

RESULT OF ANALYSIS

Date / Period of Performance of test 02/07/2015 to 09/07/2015.
**IXDLMS/QC/01/2015-16. DATED:- 10/06/2015.

Reference to protocol :- I.P-2014.(Iron & Folic Acid Tablets-IP)

Description :- Blue coloured round biconvex enteric coated tablets.

Identification :-
for Folic Acid by (HPLC) :- Complies.
for Dried Ferrous Sulphate
(by Chemical) :- Complies.
Average weight :- 411.5mg.
Uniformity of weight :- Within limit.
Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.
Disintegration time :-
1.Acidic medium:- passes the test (Limit NLT 2 hours)
2.Buffer medium:- 14 to 15 minutes. (Limit NMT 60 minutes)
Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	:- 99.1mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.524mg.	0.5mg.	0.45mg.		IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Dr. R. N. TRIPATHI
Person In Charge Of Testing

NOTE 1. The result listed refer only to the tested samples and applicable parameters. Endorsement of products is neither inferred nor implied
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STANDARD ANALTICAL [illegible]

RESULT OF ANALYSIS

Date / Period of Performance of test 02/07/2015 to 09/07/2015.
***KDLNS/QC/01/2015-16. DATED:- 19/06/2015.

Reference to protocol :- I.P-2014. (Iron & Folic Acid Tablets-IP)

Description :- Blue coloured round biconvex enteric coated tablets.

Identification :-
for Folic Acid by (HPLC) :- Complies.
For Dried Ferrous Sulphate
(by Chemical) :- Complies.

Average weight :- 610.6mg.
Uniformity of weight :- Within limit.
Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.
Disintegration time :-
1.Acidic medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 12 to 13 minutes. (Limit NMT 60 minutes)

Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	:- 99.4mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.521mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Dr. R N. TRIPATHI
Person In Charge Of Testing

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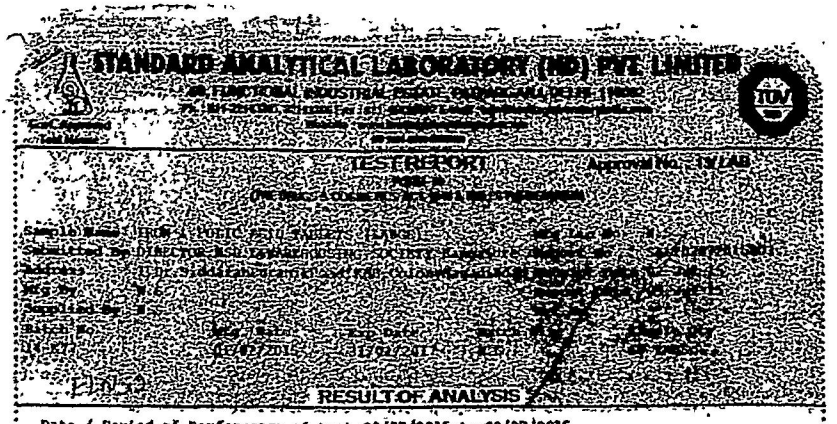

STANDARD ANALYTICAL LABORATORY (HO) PVT. LIMITED

TEST REPORT

RESULT OF ANALYSIS

Date / Period of Performance of test 02/07/2015 to 09/07/2015.

***KDLWS/QC/01/2015-16. DATED:- 19/06/2015.

Reference to protocol :- I.P-2014.(Iron & Folic Acid Tablets-IP)

Description :- Blue coloured round biconvex enteric coated tablets.

Identification :-
for Folic Acid by (HPLC) :- Complies.
For Dried Ferrous Sulphate
(by Chemical) :- Complies.
Average weight :- 413.7mg.
Uniformity of weight :- Within limit.
Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.
Disintegration time :-
1.Acidic medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 15 to 16 minutes. (Limit NMT 60 minutes)
Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elemental Ferrous iron	:- 99.3mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.517mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Dr R.N. TRIPATHI
Person In Charge Of Testing

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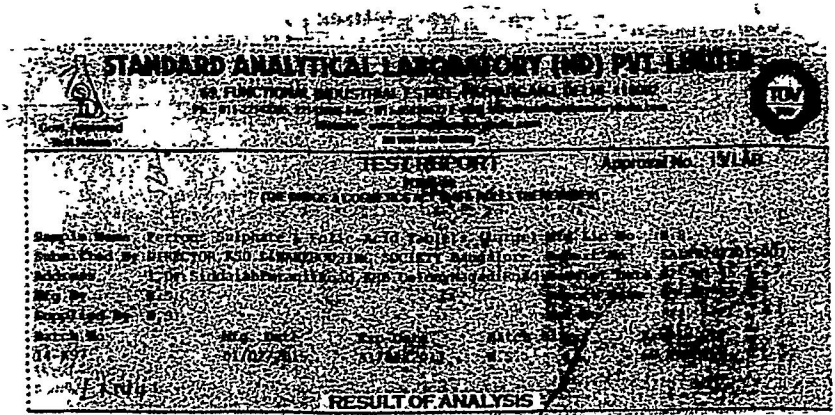

STANDARD ANALYTICAL LABORATORY (ND) PVT. LIMITED

TEST REPORT

RESULT OF ANALYSIS

Date / Period of Performance of test 02/07/2015 to 09/07/2015.
***KDLHS/QC/01/2015-16. DATED:- 19/06/2015. -

Reference to protocol :- I.P-2014.(Iron & Folic Acid Tablets-IP)

Description :- Blue coloured round biconvex enteric coated tablets.

Identiffication :-
for Folic Acid by (HPLC) :- Complies.
For Dried Ferrous Sulphate
(by Chemical) :- Complies.

Average weight :- 409.5mg.

Uniformity of weight :- Within limit.

Uniformity of content(by HPLC):-
for Folic Acid :- Within limit.

Disintegration time :-
1.Acidic medium:- Passes the test (Limit NLT 2 hours)
2.Buffer medium:- 12 to 13 minutes. (Limit NMT 60 minutes)

Ferric Iron :- Complies.

Assay :- Each enteric coated tablet contains:-

Contents of	Obtd./Av.wt.	Claim	LIMIT Lower	Upper	Method
Dried Ferrous Sulphate eq. to elecental ferrous iron	:- 99.5mg.	100.0mg.	90.0mg.	110.0mg.	IP.
Folic Acid	:- 0.515mg.	0.5mg.	0.45mg.	-	IP.

NOTE:- SAMPLE CONSUMED IN TESTING

Report:In Opinion of the undersigned,The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP.

Dr R N TRIPATHI
Person In Charge Of Testing

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